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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,036	01/20/2004	William L. Dunbar JR.	DEP 5033NP	1189

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EXAMINER	
HOFFMAN, MARY C	
ART UNIT	**PAPER NUMBER**
3733	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/761,036	DUNBAR ET AL.	
	Examiner	Art Unit	
	Mary Hoffman	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *6 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,7,11-14,18-20* is/are rejected.

7)☒ Claim(s) *3,4,8-10 and 15-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/20/2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date -.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-5 and 7-20, in the reply filed on 1/19/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/19/2006.

Drawings

The drawings are objected to because some of the informal numbers are illegible, e.g. FIG. 1, reference number for inserter shaft, and because there is extraneous matter present, e.g. FIG. 4, df. Furthermore, there are mistakes in the labeling of the figures, such as reference number "60" is used in FIG. 1 to denote the T-handle while it is used in FIG. 4 to denote the front rigid side portion. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the

appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 1-5 and 7-20 are objected to because of the following informalities:

In claim 1 there exists an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, line 1, applicant recites "A tool" with a rod-receiving portion being only functionally recited, i.e. "for a rod-receiving portion...", thus indicating that the claim is directed to the subcombination, "A tool". However, in line 8, applicant positively recites the rod-receiving portion as part of the invention, i.e. "said inserter shaft forces a spinal rod into the rod-receiving portion", thus indicating that the combination, tool and rod-receiving portion, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claim is intended to be directed, and amend

the claim such that the language thereof is consistent with this intent. For examination purposes claim 1 will be considered as being drawn to the subcombination, tool.

In claim 7, line 11, "the amount of independent motion" should be changed to --independent motion-- or --an amount of independent motion-- to make it more clear for examination purposes.

In claim 8, line 2, "than inner diameter" should be changed to --than an inner diameter-- to make it more clear for examination purposes.

In claim 11, line 3, "proximal ends" should be changed to --proximal end portions-- to be more consistent in the claims. Furthermore, in line 9, "the independent movement" should be changed to --an independent movement-- to make it more clear for examination purposes.

In claim 14, line 13, "the longitudinal axis" should be changed to --a longitudinal axis-- to make it more clear for examination purposes.

In claim 16, line 2, "the point" should be changed to --a point-- to make it more clear for examination purposes.

In claim 19, line 1, "the rotational orientation" should be changed to --a rotational orientation -- to make it more clear for examination purposes.

In claim 20, line 1, "the axial translation" should be changed to --an axial translation -- to make it more clear for examination purposes.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7, 11, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryant et al. (U.S. Patent No. 5,649,931).

Bryant et al. disclose a tool (see FIGS. 4 and 5, ref. #10) comprising a body (ref. #14) having a proximal end portion and a distal end portion. The distal end includes a first and second flexible branch (ref. #30). An inserter shaft (ref. #16) is slidably received within the body, the inserter shaft having a distal end. The tool also comprises a threaded collar (ref. #18), capable of coupling the body and the inserter shaft. The inserter shaft is capable of forcing a spinal rod into the rod-receiving portion of the implant. The body further comprises external threads capable of engaging with the threaded collar (ref. #36). A guide mechanism (ref. #20) is capable of co-operating with the shaft and the body whereby the guide mechanism limits the independent movement of the shaft within the body. Bryant et al further disclose a tool (see FIGS. 4 and 5, ref. #10) comprising a body (ref. #14) having a proximal and distal end portion, wherein an interior channel extending between the distal and proximal ends, the distal end portion having flexible branches and the proximal end portion having external threads (ref. #36). An inserter shaft (ref. #16), capable of being slidable within the interior channel of the body, has a proximal end portion, a distal end portion, and a transition zone located

between the distal and proximal end portions, the transition zone having a diameter larger than the proximal end portions, and a collar having an internally threaded hollow body (ref. #38) and a central shaft attached to the hollow body (see unthreaded portion of collar ref. #18), wherein the central shaft limits the amount of independent motion between the inserter shaft and the collar. The independent movement limited is the rotational orientation and axial translation of the inserter shaft with respect to the body.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryant et al. (U.S. Patent No. 5,649,931).

Bryant et al. disclose a tool (see FIGS. 4 and 5, ref. #10) comprising a body (ref. #14) having a proximal end portion and a distal end portion. The distal end includes a first and second flexible branch (ref. #30). An inserter shaft (ref. #16) is slidably received within the body, the inserter shaft having a distal end. The tool also comprises a threaded collar (ref. #18), capable of coupling the body and the inserter shaft. The inserter shaft is capable of forcing a spinal rod into the rod-receiving portion of the implant. The tool further comprises an outer sleeve rotatably and slidably mounted onto the distal end of the body, the sleeve being capable of being movable between a first and second position (ref. #18).

Claims 11-13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker (U.S. Patent No. 2,248,054).

Becker discloses a tool (see FIGS. 1-5) comprising a body (ref. #5) having a proximal and distal end portion, the distal end portion having branches. An interior channel extends between the distal and proximal end portions. An inserter shaft (ref.

#12), capable of being slidable within the interior channel of the body, has a proximal end portion and a distal end portion. A guide mechanism is capable of co-operating with the shaft and the body whereby the guide mechanism limits the independent movement of the shaft within the body. The guide mechanism comprises a channel (ref. #10) and a pin (ref. #11) capable of fitting within the channel. The channel is located on the body and the pin is capable of fitting within the channel is located on the shaft. The pin and channel prevent the shaft from being removed from the body.

Claims 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Torode et al. (U.S. Patent Publication 2003/0004519 A1).

Torode et al. disclose a tool (see 7A) comprising a body (ref. #700) having a proximal and distal end portion, the distal end portion having branches. An interior channel extends between the distal and proximal end portions. An inserter shaft (ref. #710), capable of being slidable within the interior channel of the body, has a proximal end portion and a distal end portion. A guide mechanism is capable of co-operating with the shaft and the body whereby the guide mechanism limits the independent movement of the shaft within the body. The guide mechanism comprises a channel and a pin (ref. #734a) capable of fitting within the channel. The channel is located on the body and the pin is capable of fitting within the channel is located on the shaft. The channel extends parallel to the longitudinal axis of the body.

Allowable Subject Matter

Claims 3, 4, 8-10, and 15-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and rewritten to overcome the claims objections due to minor informalities set forth in this office action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached form PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER